

CLAIMS

What is claimed is:

1. (Currently amended) An injectable depot composition comprising:
 - (a) a polymer matrix comprising a plurality of bioerodible, biocompatible polymers wherein each polymer of the plurality of polymers has a specified average molecular weight; the polymer matrix having a broad molecular weight distribution of the plurality of polymers;
 - (b) a solvent having a miscibility in water of less than or equal to 7% at 25°C, in an amount effective to plasticize the plurality of polymers and form a gel therewith; and
 - (c) a beneficial agent dissolved or dispersed in the gel.

2. (Currently amended) An injectable depot composition comprising:
 - (a) a polymer matrix comprising a plurality of bioerodible, biocompatible polymers; wherein a first of the plurality of polymers is a low molecular weight (LMW) polymer; and a second of the plurality of polymers is a high molecular weight (HMW) polymer; the polymer matrix having a bimodal molecular weight distribution of the plurality of polymers;
 - (b) a solvent having a miscibility in water of less than or equal to 7% at 25°C, in an amount effective to plasticize the plurality of polymers and form a gel therewith; and
 - (c) a beneficial agent dissolved or dispersed in the gel.

3. (Currently amended) An injectable depot composition comprising:
 - (a) a polymer matrix comprising a plurality of bioerodible, biocompatible polymers; wherein a first of the plurality of polymers is a low molecular weight (LMW) polymer; a second of the plurality of polymers is a high molecular weight (HMW) polymer; a third of the plurality of polymers is a medium molecular weight (MMW) polymer; the polymer matrix having a broad, multimodal molecular weight distribution of the plurality of polymers;
 - (b) a solvent having a miscibility in water of less than or equal to 7% at 25°C, in an amount effective to plasticize the plurality of polymers and form a gel therewith; and
 - (c) a beneficial agent dissolved or dispersed in the gel.

4. (Original) The injectable depot composition of claims 1, 2 or 3, wherein the solvent is a solvent selected from the group consisting of aromatic alcohols, esters of aromatic acids, aromatic ketones, and mixtures thereof.

5. (Currently amended) The injectable depot composition of claim 1, wherein the polymer matrix has a multimodal molecular weight distribution of the plurality of polymers, wherein a first of the plurality of polymers is a low molecular weight (LMW) polymer having an average molecular weight of about 3,000 to about 10,000; a second of the plurality of polymers is a high molecular weight (HMW) polymer having an average molecular weight of greater than 30,000; and a third of the plurality of polymers is a medium molecular weight (MMW) polymer having an average molecular weight of between about 10,000 and about 30,000.

6. (Currently amended) The injectable depot composition of claim 5, wherein the polymer matrix comprises about 0 wt% to about 95 wt% of the low molecular weight (LMW) polymer; about 0 wt% to about 95 wt% of the high molecular weight (HMW) polymer; and about 0 wt% to about 95 wt% of the medium molecular weight (MMW) polymer.

7. (Currently amended) The composition of claim 1, wherein the plurality of polymers is selected from the group consisting of polylactides, polyglycolides, polyanhydrides, polyamines, polyesteramides, polyorthoesters, polydioxanones, polyacetals, polyketals, polycarbonates, polyphosphoesters, polyoxaesters, polyorthocarbonates, polyphosphazenes, succinates, poly(malic acid), poly(amino acids), polyvinylpyrrolidone, polyethylene glycol, polyhydroxycellulose, polyphosphoesters, chitin, chitosan, and copolymers, terpolymers and mixtures thereof.

8. (Currently amended) The composition of claim 7, wherein each polymer is a lactic acid-based polymer.

9. (Currently amended) The composition of claim 8, wherein each polymer is a copolymer of lactic acid and glycolic acid.

10. (Currently amended) The composition of claim 7, comprising about 5 wt% to about 90 wt% of a biodegradable, biocompatible lactic acid-based polymer.

11. (Currently amended) The composition of claim 10, comprising about 25 wt% to about 80 wt% of the biodegradable, biocompatible lactic acid-based polymer.

12. (Currently amended) The composition of claim 4, wherein the solvent has a miscibility in water of less than or equal to 5 wt% at 25°C.

13. (Currently amended) The composition of claim 12, wherein the solvent has a miscibility in water of less than or equal to 3 wt% at 25°C.

14. (Currently amended) The composition of claim 13, wherein the solvent has a miscibility in water of less than or equal to 1 wt% at 25°C.

15. (Currently amended) The composition of claim 14, wherein the solvent has a miscibility in water of less than or equal to 0.5 wt% at 25°C.

16. (Original) The injectable depot composition of claim 4, wherein aromatic alcohol has the structural formula (I)



in which Ar is a substituted or unsubstituted aryl or heteroaryl group, n is zero or 1, and L is a linking moiety.

17. (Original) The composition of claim 16, wherein Ar is monocyclic aryl or heteroaryl, n is 1, and L is lower alkylene optionally containing at least one heteroatom.

18. (Original) The composition of claim 17, wherein Ar is monocyclic aryl and L is lower alkylene.

19. (Original) The composition of claim 18, wherein Ar is phenyl and L is methylene.
20. (Original) The composition of claim 19, wherein the aromatic acid is benzyl alcohol.
21. (Original) The composition of claim 4, wherein the ester of an aromatic acid is a lower alkyl ester or an aralkyl ester of benzoic acid.
22. (Original) The composition of claim 21, wherein the ester of an aromatic acid is benzyl benzoate and the lower alkyl ester of an aromatic acid is ethyl benzoate.
23. (Currently amended) The composition of claim 4, wherein the solvent is a mixture of an aromatic alcohol and an ester of an aromatic acid.
24. (Currently amended) The composition of claim 23, wherein the ratio of the aromatic alcohol to the ester of the aromatic acid is in the range of about 1% to about 99% by weight.
25. (Currently amended) The composition of claim 24, wherein the ratio of the aromatic alcohol to the ester of the aromatic acid is in the range of about 10% to about 90% by weight.
26. (Currently amended) The composition of claim 25, wherein the ratio of the aromatic alcohol to the ester of the aromatic acid is in the range of about 20% to about 80% by weight.

27. (Currently amended) The composition of claim 1, wherein the solvent is selected from the group consisting of triacetin, diacetin, tributyrin, triethyl citrate, tributyl citrate, acetyl triethyl citrate, acetyl tributyl citrate, triethylglycerides, triethyl phosphate, diethyl phthalate, diethyl tartrate, mineral oil, polybutene, silicone fluid, glycerin, ethylene glycol, polyethylene glycol, octanol, ethyl lactate, propylene glycol, propylene carbonate, ethylene carbonate, butyrolactone, ethylene oxide, propylene oxide, N-methyl-2-pyrrolidone, 2-pyrrolidone, glycerol formal, methyl acetate, ethyl acetate, methyl ethyl ketone, dimethylformamide, dimethyl sulfoxide, tetrahydrofuran, caprolactam, decylmethylsulfoxide, oleic acid, and 1-dodecylazacyclo-heptan-2-one, and mixtures thereof.

28. (Currently amended) An injectable depot composition for systemic delivery of a beneficial agent to a subject in a controlled manner comprising:

(a) a polymer matrix comprising a plurality of bioerodible, biocompatible polymers; wherein a first of the plurality of polymers is a low molecular weight (LMW) polymer; a second of the plurality of polymers is a high molecular weight (HMW) polymer; a third of the plurality of polymers is a medium molecular weight (MMW) polymer; the polymer matrix having a broad, multimodal molecular weight distribution of the plurality of polymers;

(b) a solvent having a miscibility in water of less than or equal to 7% at 25°C, in an amount effective to plasticize the plurality of polymers and form a gel therewith; and

(c) a beneficial agent dissolved or dispersed in the gel.

29. (Currently amended) An injectable depot composition for sustained delivery of a beneficial agent to a subject comprising:

(a) a polymer matrix comprising a plurality of bioerodible, biocompatible polymers; wherein a first of the plurality of polymers is a low molecular weight (LMW) polymer; a second of the plurality of polymers is a high molecular weight (HMW) polymer; a third of the plurality of polymers is a medium molecular weight (MMW) polymer; the polymer matrix having a broad, multimodal molecular weight distribution of the plurality of polymers;

(b) a solvent having a miscibility in water of less than or equal to 7% at 25°C, in an amount effective to plasticize the plurality of polymers and form a gel therewith; and

(c) a beneficial agent dissolved or dispersed in the gel;

wherein the beneficial agent is delivered systemically in a controlled manner over a duration of one year.

30. (Currently amended) An injectable depot composition for local delivery of a beneficial agent to a subject in a controlled manner comprising:

(a) a polymer matrix comprising a plurality of bioerodible, biocompatible polymers; wherein a first of the plurality of polymers is a low molecular weight (LMW) polymer; a second of the plurality of polymers is a high molecular weight (HMW) polymer; a third of the plurality of polymers is a medium molecular weight (MMW) polymer; the polymer matrix having a broad, multimodal molecular weight distribution of the plurality of polymers;

(b) a solvent having a miscibility in water of less than or equal to 7% at 25°C, in an amount effective to plasticize the plurality of polymers and form a gel therewith; and

(c) a beneficial agent dissolved or dispersed in the gel.

31. (Currently amended) An injectable depot composition for sustained delivery of a beneficial agent to a subject comprising:

(a) a polymer matrix comprising a plurality of bioerodible, biocompatible polymers; wherein a first of the plurality of polymers is a low molecular weight (LMW) polymer; a second of the plurality of polymers is a high molecular weight (HMW) polymer; a third of the plurality of polymers is a medium molecular weight (MMW) polymer; the polymer matrix having a broad, multimodal molecular weight distribution of the plurality of polymers;

(b) a solvent having a miscibility in water of less than or equal to 7% at 25°C, in an amount effective to plasticize the plurality of polymers and form a gel therewith; and

(c) a beneficial agent dissolved or dispersed in the gel;

wherein the beneficial agent is delivered locally in a controlled manner over a duration of up to one year.

32. (Original) The injectable depot composition of any one of claims 28, 29, 30 or 31, wherein the solvent is a solvent selected from the group consisting of aromatic alcohols, esters of aromatic acids, aromatic ketones, and mixtures thereof.

33. (Currently amended) The injectable depot composition of claim 32, wherein the polymer matrix has a multimodal molecular weight distribution of the plurality of polymers, wherein a first of the plurality of polymers is a low molecular weight (LMW) polymer having an average molecular weight of about 3,000 to about 10,000; a second of the plurality of polymers is a high molecular weight (HMW) polymer having an average molecular weight of greater than 30,000; and a third of the plurality of polymers is a medium molecular weight (MMW) polymer having an average molecular weight of between about 10,000 and about 30,000.

34. (Currently amended) The injectable depot composition of claim 33, wherein the polymer matrix comprises about 0 wt% to about 95 wt% of the low molecular weight (LMW) polymer; about 0 wt% to about 95 wt% of the high molecular weight (HMW) polymer; and about 0 wt% to about 95 wt% of the medium molecular weight (MMW) polymer.

35. (Currently amended) The composition of claim 32, wherein the plurality of polymers is selected from the group consisting of polylactides, polyglycolides, polyanhydrides, polyamines, polyesteramides, polyorthoesters, polydioxanones, polyacetals, polyketals, polycarbonates, polyphosphoesters, polyoxaesters, polyorthocarbonates, polyphosphazenes, succinates, poly(malic acid), poly(amino acids), polyvinylpyrrolidone, polyethylene glycol, polyhydroxycellulose, polyphosphoesters, chitin, chitosan, and copolymers, terpolymers and mixtures thereof.

36. (Currently amended) The composition of claim 35, wherein each polymer is a lactic acid-based polymer.

37. (Currently amended) The composition of claim 36, wherein each polymer is a copolymer of lactic acid and glycolic acid.

38. (Currently amended) The composition of claim 35, comprising about 5 wt% to about 90 wt% of a biodegradable, biocompatible lactic acid-based polymer.

39. (Currently amended) The composition of claim 38, comprising about 25 wt% to about 80 wt% of the biodegradable, biocompatible lactic acid-based polymer.

40. (Currently amended) The composition of claim 32, wherein the solvent has a miscibility in water of less than or equal to 5 wt% at 25°C.

41. (Currently amended) The composition of claim 40, wherein the solvent has a miscibility in water of less than or equal to 3 wt% at 25°C.

42. (Currently amended) The composition of claim 41, wherein the solvent has a miscibility in water of less than or equal to 1 wt% at 25°C.

43. (Currently amended) The composition of claim 42, wherein the solvent has a miscibility in water of less than or equal to 0.5 wt% at 25°C.

44. (Currently amended) The injectable depot composition of claim 32, wherein the aromatic alcohol has the structural formula (I)



in which Ar is a substituted or unsubstituted aryl or heteroaryl group, n is zero or 1, and L is a linking moiety.

45. (Original) The composition of claim 44, wherein Ar is monocyclic aryl or heteroaryl, n is 1, and L is lower alkylene optionally containing at least one heteroatom.

46. (Original) The composition of claim 45, wherein Ar is monocyclic aryl and L is lower alkylene.

47. (Original) The composition of claim 46, wherein Ar is phenyl and L is methylene.

48. (Original) The composition of claim 47, wherein the aromatic acid is benzyl alcohol.

49. (Currently amended) The composition of claim 32, wherein the ester of the aromatic acid is a lower alkyl ester or an aralkyl ester of benzoic acid.

50. (Currently amended) The composition of claim 49, wherein the ester of the aromatic acid is benzyl benzoate and the lower alkyl ester of an aromatic acid is ethyl benzoate.

51. (Currently amended) The composition of claim 32, wherein the solvent is a mixture of the aromatic alcohol and the ester of the aromatic acid.

52. (Currently amended) The composition of claim 51, wherein a ratio of the aromatic alcohol to the ester of the aromatic acid is in the range of about 1% to about 99% by weight.

53. (Currently amended) The composition of claim 52, wherein the ratio of the aromatic alcohol to the ester of the aromatic acid is in the range of about 10% to about 90% by weight.

54. (Currently amended) The composition of claim 53, wherein the ratio of the aromatic alcohol to the ester of the aromatic acid is in the range of about 20% to about 80% by weight.

55. (Currently amended) The composition of claim 32, wherein the solvent is selected from the group consisting of triacetin, diacetin, tributyrin, triethyl citrate, tributyl citrate, acetyl triethyl citrate, acetyl tributyl citrate, triethylglycerides, triethyl phosphate, diethyl phthalate, diethyl tartrate, mineral oil, polybutene, silicone fluid, glycerin, ethylene glycol, polyethylene glycol, octanol, ethyl lactate, propylene glycol, propylene carbonate, ethylene carbonate, butyrolactone, ethylene oxide, propylene oxide, N-methyl-2-pyrrolidone, 2-pyrrolidone, glycerol formal, methyl acetate, ethyl acetate, methyl ethyl ketone, dimethylformamide, dimethyl sulfoxide, tetrahydrofuran, caprolactam, decylmethylsulfoxide, oleic acid, and 1-dodecylazacyclo-heptan-2-one, and mixtures thereof.

56. (Currently amended) A method of administering a beneficial agent to a subject in a controlled manner over a duration of up to one year, comprising administering an injectable depot composition comprising:

(a) a polymer matrix comprising a plurality of bioerodible, biocompatible polymers; wherein a first of the plurality of polymers is a low molecular weight (LMW) polymer; a second of the plurality of polymers is a high molecular weight (HMW) polymer; a third of the plurality of polymers is a medium molecular weight (MMW) polymer; the polymer matrix having a broad, multimodal molecular weight distribution of the plurality of polymers;

(b) a solvent having a miscibility in water of less than or equal to 7% at 25°C, in an amount effective to plasticize the plurality of polymers and form a gel therewith; and

(c) a beneficial agent dissolved or dispersed in the gel.

57. (Currently amended) A method of administering a beneficial agent to a subject comprising administering an injectable depot composition comprising:

(a) a polymer matrix comprising a plurality of bioerodible, biocompatible polymers; wherein a first of the plurality of polymers is a low molecular weight (LMW) polymer; a second of the plurality of polymers is a high molecular weight (HMW) polymer; a third of the plurality of polymers is a medium molecular weight (MMW) polymer; the polymer matrix having a broad, multimodal molecular weight distribution of the plurality of polymers;

(b) a solvent having a miscibility in water of less than or equal to 7% at 25°C, in an amount effective to plasticize the plurality of polymers and form a gel therewith; and

(c) a beneficial agent dissolved or dispersed in the gel;
wherein the beneficial agent is delivered systemically in a controlled manner over a duration of up to one year.

58. (Currently amended) A method of locally administering a beneficial agent to a subject in a controlled manner over a duration of up to one year, comprising administering an injectable depot composition comprising:

(a) a polymer matrix comprising a plurality of bioerodible, biocompatible polymers; wherein a first of the plurality of polymers is a low molecular weight (LMW) polymer; a second of the plurality of polymers is a high molecular weight (HMW) polymer; a third of the plurality of polymers is a medium molecular weight (MMW) polymer; the polymer matrix having a broad, multimodal molecular weight distribution of the plurality of polymers;

(b) a solvent having a miscibility in water of less than or equal to 7% at 25°C, in an amount effective to plasticize the plurality of polymers and form a gel therewith; and

(c) a beneficial agent dissolved or dispersed in the gel;
the system releasing within 24 hours after implantation not greater than 20% by weight of the beneficial agent to be delivered over the duration of a delivery period.

59. (Currently amended) A method of administering a beneficial agent to a subject comprising administering an injectable depot composition comprising:

(a) a polymer matrix comprising a plurality of bioerodible, biocompatible polymers; wherein a first of the plurality of polymers is a low molecular weight (LMW) polymer; a second of the plurality of polymers is a high molecular weight (HMW) polymer; a third of the plurality of polymers is a medium molecular weight (MMW) polymer; the polymer matrix having a broad, multimodal molecular weight distribution of the plurality of polymers;

(b) a solvent having a miscibility in water of less than or equal to 7% at 25°C, in an amount effective to plasticize the plurality of polymers and form a gel therewith; and

(c) a beneficial agent dissolved or dispersed in the gel;
wherein the beneficial agent is delivered locally in a controlled manner over a duration of up to one year.

60. (Original) The injectable depot composition of any one of claims 56, 57, 58 or 59, wherein the solvent is a solvent selected from the group consisting of aromatic alcohols, esters of aromatic acids, aromatic ketones, and mixtures thereof.

61. (Currently amended) The injectable depot composition of claim 60, wherein the polymer matrix has a multimodal molecular weight distribution of the plurality of polymers, wherein a first of the plurality of polymers is a low molecular weight (LMW) polymer having an average molecular weight of about 3,000 to about 10,000; a second of the plurality of polymers is a high molecular weight (HMW) polymer having an average molecular weight of greater than 30,000; and a third of the plurality of polymers is a medium molecular weight (MMW) polymer having an average molecular weight of between about 10,000 to about 30,000.

62. (Currently amended) The injectable depot composition of claim 61, wherein the polymer matrix comprises about 0 wt% to about 95 wt% of the low molecular weight (LMW) polymer; about 0 wt% to about 95 wt% of the high molecular weight (HMW) polymer; and about 0 wt% to about 95 wt% of the medium molecular weight (MMW) polymer.

63. (Currently amended) The composition of claim 60, wherein the plurality of polymers is selected from the group consisting of polylactides, polyglycolides, polyanhydrides, polyamines, polyesteramides, polyorthoesters, polydioxanones, polyacetals, polyketals, polycarbonates, polyphosphoesters, polyoxaesters, polyorthocarbonates, polyphosphazenes, succinates, poly(malic acid), poly(amino acids), polyvinylpyrrolidone, polyethylene glycol, polyhydroxycellulose, polyphosphoesters, chitin, chitosan, and copolymers, terpolymers and mixtures thereof.

64. (Currently amended) The composition of claim 63, wherein each polymer is a lactic acid-based polymer.

65. (Currently amended) The composition of claim 64, wherein each polymer is a copolymer of lactic acid and glycolic acid.

66. (Currently amended) The composition of claim 63, comprising about 5 wt% to about 90 wt% of a biodegradable, biocompatible lactic acid-based polymer.

67. (Currently amended) The composition of claim 66, comprising about 25 wt% to about 80 wt% of the biodegradable, biocompatible lactic acid-based polymer.

68. (Currently amended) The composition of claim 60, wherein the solvent has a miscibility in water of less than or equal to 5 wt% at 25°C.

69. (Currently amended) The composition of claim 68, wherein the solvent has a miscibility in water of less than or equal to 3 wt% at 25°C.

70. (Currently amended) The composition of claim 69, wherein the solvent has a miscibility in water of less than or equal to 1 wt% at 25°C.

71. (Currently amended) The composition of claim 70, wherein the solvent has a miscibility in water of less than or equal to 0.5 wt% at 25°C.

72. (Currently amended) The injectable depot composition of claim 60, wherein the aromatic alcohol has the structural formula (I)



in which Ar is a substituted or unsubstituted aryl or heteroaryl group, n is zero or 1, and L is a linking moiety.

73. (Original) The composition of claim 72, wherein Ar is monocyclic aryl or heteroaryl, n is 1, and L is lower alkylene optionally containing at least one heteroatom.

74. (Original) The composition of claim 73, wherein Ar is monocyclic aryl and L is lower alkylene.

75. (Original) The composition of claim 74, wherein Ar is phenyl and L is methylene.
76. (Original) The composition of claim 75, wherein the aromatic acid is benzyl alcohol.
77. (Currently amended) The composition of claim 60, wherein the ester of the aromatic acid is a lower alkyl ester or an aralkyl ester of benzoic acid.
78. (Currently amended) The composition of claim 77, wherein the ester of the aromatic acid is benzyl benzoate and the lower alkyl ester of an aromatic acid is ethyl benzoate.
79. (Currently amended) The composition of claim 60, wherein the solvent is a mixture of the aromatic alcohol and the ester of the aromatic acid.
80. (Currently amended) The composition of claim 79, wherein a ratio of the aromatic alcohol to the ester of the aromatic acid is in the range of about 1% to about 99% by weight.
81. (Currently amended) The composition of claim 80, wherein the ratio of the aromatic alcohol to the ester of the aromatic acid is in the range of about 10% to about 90% by weight.
82. (Currently amended) The composition of claim 81, wherein the ratio of the aromatic alcohol to the ester of the aromatic acid is in the range of about 20% to about 80% by weight.

83. (Currently amended) The composition of claim 60, wherein the solvent is selected from the group consisting of triacetin, diacetin, tributyrin, triethyl citrate, tributyl citrate, acetyl triethyl citrate, acetyl tributyl citrate, triethylglycerides, triethyl phosphate, diethyl phthalate, diethyl tartrate, mineral oil, polybutene, silicone fluid, glycerin, ethylene glycol, polyethylene glycol, octanol, ethyl lactate, propylene glycol, propylene carbonate, ethylene carbonate, butyrolactone, ethylene oxide, propylene oxide, N-methyl-2-pyrrolidone, 2-pyrrolidone, glycerol formal, methyl acetate, ethyl acetate, methyl ethyl ketone, dimethylformamide, dimethyl sulfoxide, tetrahydrofuran, caprolactam, decylmethylsulfoxide, oleic acid, and 1-dodecylazacyclo-heptan-2-one, and mixtures thereof.

84. (Currently amended) A kit for administration of a beneficial agent to a subject comprising:

(a) a polymer matrix comprising a plurality of bioerodible, biocompatible polymers; wherein a first of the plurality of polymers is a low molecular weight (LMW) polymer; a second of the plurality of polymers is a high molecular weight (HMW) polymer; a third of the plurality of polymers is a medium molecular weight (MMW) polymer; the polymer matrix having a broad, multimodal molecular weight distribution of the plurality of polymers;

(b) a solvent having a miscibility in water of less than or equal to 7% at 25°C, in an amount effective to plasticize the plurality of polymers and form a gel therewith;

(c) a beneficial agent dissolved or dispersed in the gel; and optionally, one or more of the following:

(d) an emulsifying agent;

(e) a pore former;

(f) a solubility modulator for the beneficial agent, optionally associated with the beneficial agent; and

(g) an osmotic agent;

wherein at least the beneficial agent, optionally associated with the solubility modulator, is maintained separated from the solvent until a time of administration of the beneficial agent to a subject.

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